repeat sequences, please see U.S. Pat. No. 5, 741,645 to Orr et al. and U.S. Pat. No. 5,552,282 to Caskey.et al., included with this response.

Claim 6 is cancelled and claim 5 is now amended to recite specific high stringency wash conditions.

Claim 8 is amended to recite the language recommended by the Examiner solely to further prosecution. It is Applicants' position that once a novel and nonobvious gene has been identified and a patent to the gene has issued, Applicants' have have a stake in the invention whether the gene is a host cell or in an isolated host cell and therefore, that Applicant's claim ownership as to at least a part of any animal that includes the once isolated gene whether or not this work is completed at the time because methods of producing transgenic animals are well known in the art.

Claim 12 is amended to recite a kit to detect alterations in the length of the CAG repeat sequence. Support for the amendments to this claim are found at page 33, line 35 of the specification and at FIGURE 6A.

For these reasons Applicants request that the rejections under 35 U.S.C. § 112, first paragraph be withdrawn.

35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 4-5, 12, 40, 43, 49 and 52-54 under 35 U.S.C. § 112, second paragraph. Claims 4, 5, 12, 40 and 43 have been amended for clarification. Claim 49 is now directed to a DNA fragment produced by an amplification method that recites the steps of the now cancelled claim 46. The amplification step of this claim is disclosed throughout the specification and detailed in the examples. Amended claim 52 recites a DNA fragment that includes the nucleic acid sequence of SCA2-A and a CAG repeat sequence. There is no new matter in this claim as FIGURE 6A is one example of an SCA-2 gene comprising the nucleic acid sequence of SCA2-A and a CAG repeat sequence. Other SCA-2 genes have been detected that include alterations in the length of the CAG repeat sequence as stated in the specification at page 33, first paragraph.

The Examiner is requiring unnecessary limitations to claim 52. The specification clearly teaches a class of genes that comprise the nucleic acid sequence of SCA2A and a CAG repeat sequence and the specification teaches the production of isolated amplification fragments from the SCA2 gene of varying lengths obtained from 8 different gene lineages using and individually testing more than 8 different individuals. Applicants are entitled to a patent scope

that includes the amplified gene fragments of the CAG repeat sequence. The Examiner cautions against introducing new matter but the presence of the CAG repeat sequence, the location of the CAG sequence in SCA2, the primer SCA2A, the location of SCA2A in SCA2, and the use of an amplification reaction to amplify the CAG repeat sequence as a test for determining the presence or absence of SCA2 are all fully described in the patent specification as specifically enumerated throughout this action. No new matter has been introduced into this claim.

For these reasons Applicants request that the rejections under 35 U.S.C. § 112, second paragraph be withdrawn.

Rejections under 35 U.S.C. 102(b)

The Examiner has prepared a number of rejections under 35 U.S.C. 102(b) and states that "Applicant is being given benefit to only the instant filing date, namely 10/8/96, as neither of the provisional applications disclose the nucleic acid sequences found in the instant application." Such a statement is absolutely incorrect. Even a cursory review of the first provisional application filed on May 8, 1996 would reveal at least one nucleic acid sequence, see for example FIGURE 2, that is covered by a variety of claims now under examination.

The Examiner has rejected claims 1-4, 10, 12, 13 and 40 under 35 U.S.C. 102(a) as anticipated by EST Accession No. W39162 yet the EST does not include a CAG repeat sequence. Therefore there is no anticipation under 35 U.S.C. 102(a). Further, the EST entry has an accession date of May 15, 1996 while the present invention has a priority date of at least May 8, 1996.

The Examiner has rejected claims 5, 10-12, 40, 43 and 49 under 35 U.S.C. 102(b) as being anticipated by Orr et al.(*Nature Genetics* 4:221-226, 1993). The Examiner is incorrect. claim 5 recites a DNA fragment having a nucleic acid sequence obtained from the isolated nucleic acid sequence ultimately dependant on claim 1, wherein the DNA hybridizes under high stringency conditions, comprising a final stringency of 0.2 SSC, 0.1x SDS at 65 °C, to the SCA2 coding portion of nucleotides 1-516 of SEQ ID NO:1 or nucleotides 163-4098 of SEQ ID NO:2 or SEQ ID NO:4. The SCA1 gene does not hybridize under high stringency conditions to SCA2 and the nucleic acid sequence GGGCCCCTCACCATGTCG required in claim 1 of the present invention is not found in SCA1. Further, the specification states at page 32, line 20 that the SCA2 gene shows no homology to SCA1 and SCA3. Again, there is no anticipation under 35 U.S.C. 102(b).

The Examiner has further rejected claims 5, 10-12, 40, 43 and 49 under 35 U.S.C.

102(b) as anticipated by Kawaguchi et al. Claim 12 relates to a kit for detecting alterations in a CAG repeat sequence of SCA2 and claim 40 requires at least two single strand DNA primers for the amplification of an SCA2 CAG repeat sequence, wherein said primers comprise a nucleic acid sequence derived from the nucleic acid of SEQ ID NO:2 or SEQ ID NO:4. The CAG repeat probe does not anticipate claims 12 and 40 because the claims require amplification of a CAG repeat region to detect alterations in a CAG repeat sequence (claim 12) or requires two primers for the amplification of an SCA2 CAG repeat sequence (claim 40). A CAG repeat primer, such as that of Kawaguchi, would not function as an amplification primer to detect a CAG repeat sequence in an SCA2 gene since the primer contains that portion of the gene that is required for amplification. Further, identity is required under 35 U.S.C. 102(b) and the 5' portion of the Kawaguchi et al. probe is not 5' of the CAG repeat sequence of SCA2. Claim 49 is now amended to recite a DNA fragment that is the product of the process of claim 49. The Kawaguchi et al. primer would not be a product of the process of claim 49.

For these reasons Applicants respectfully request withdrawal of the rejections under 35 U.S.C. 102(a) and 102(b).

CONCLUSION

It is respectfully submitted that the pending claims (claims 1-5, 7-13, 40, 43, 49, 52-54) are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO THE ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, D.C. 20231.

ON May 22, 1998
DATE OF DEPOSIT

Myra H. McCormack

Myra H. McCormack

May 22, 1998
Date

MHM:jrp

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